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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,473

Applicant(s)

VALE ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, 4, 6-8, in so far as they are drawn to DNA encoding a polypeptide of SEQ ID NO:10, vectors and host cells, classified in class 435, subclass 69.1, for example.
 - II. Claims 1, 3-5, 7-8, in so far as they are drawn to DNA encoding a polypeptide of SEQ ID NO:11, vectors and host cells, classified in class 435, subclass 69.1, for example.
 - III. Claims 9, 13, 32-37, 39-46, in so far as they are drawn to a polypeptide of SEQ ID NO:10, classified in class 530, subclass 350, for example.
 - IV. Claims 9-10, 13, 32-46, in so far as they are drawn to a polypeptide of SEQ ID NO:11, classified in class 530, subclass 350, for example.
 - V. Claims 11-12, in so far as they are drawn to an antibody to a polypeptide of SEQ ID NO:10, classified in class 530, subclass 387.1, for example.
 - VI. Claims 11-12, in so far as they are drawn to an antibody to a polypeptide of SEQ ID NO:11, classified in class 530, subclass 387.1, for example.
 - VII. Claims 14-15, in so far as they are drawn to a method of treatment by administering a polypeptide of SEQ ID NO:10, classified in class 514, subclass 2, for example.

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- VIII. Claims 14-15, in so far as they are drawn to a method of treatment by administering a polypeptide of SEQ ID NO:11, classified in class 514, subclass 2, for example.
- IX. Claims 16-18, 20, 22-24, in so far as they are drawn to DNA encoding a polypeptide of SEQ ID NO:2, vectors and host cells, classified in class 435, subclass 69.1, for example.
- X. Claims 16-17, 19-24, in so far as they are drawn to DNA encoding a polypeptide of SEQ ID NO:3, vectors and host cells, classified in class 435, subclass 69.1, for example.
- XI. Claims 25, 29, 32-37, in so far as they are drawn to a polypeptide of SEQ ID NO:2, classified in class 530, subclass 350, for example.
- XII. Claims 25-26, 29, 32-37, in so far as they are drawn to a polypeptide of SEQ ID NO:3, classified in class 530, subclass 350, for example.
- XIII. Claims 27-28, in so far as they are drawn to an antibody to a polypeptide of SEQ ID NO:2, classified in class 530, subclass 387.1, for example.
- XIV. Claims 27-28, in so far as they are drawn to an antibody to a polypeptide of SEQ ID NO:3, classified in class 530, subclass 387.1, for example.
- XV. Claims 30-31, in so far as they are drawn to a method of treatment by administration of polypeptide of SEQ ID NO:2, classified in class 514, subclass 2, for example.

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XVI. Claims 30-31, in so far as they are drawn to a method of treatment by administration of polypeptide of SEQ ID NO:3, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I and II), (III and IV), (V and VI), (IX and X), (XI and XII) and (XIII and XIV), respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the DNA, polypeptides and antibodies of Groups (I and II), (III and IV), (V and VI), (IX and X), (XI and XII), (XIII and XIV), respectively, have different chemical structure, not required for each other and, therefore, constitute patentably distinct inventions.

3. Inventions (I, II, IX, X) and (III, IV, XI, XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Groups (I, II, IX, X) and polypeptides of Groups (III, IV, XI, XII) are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.

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4. Inventions (I, II, IX, X) and (V, VI, XIII, XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, antibodies of Groups (V, VI, XIII, XIV) can also be used in materially different methods, such as in various diagnostic (e.g. as a probe in immunoassays or immunochromatography), or therapeutic methods.

5. Inventions (III, IV, XI, XII) and (V, VI, XIII, XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups (III, IV, XI, XII) and antibodies of Groups (V, VI, XIII, XIV) are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and entirely different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein.

6. Inventions (III, IV, XI, XII) and (VII, VIII, XV, XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

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using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups (III, IV, XI, XII) could be used in an entirely different manner such as for the production of antibodies rather than in the methods of Groups (VII, VIII, XV, XVI).

7. Inventions VII, VIII, XV and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally distinct elements, are not required one for the other, and therefore constitute patentably distinct inventions.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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9. In case Group VII, VIII, XV or XVI is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different pathophysiological conditions (claims 15 and 31).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14 and 30, respectively, are generic.

10. In case Group XI or XII is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different modifications of the protein (claim 35)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 32 is generic.

11. In case Group III or IV is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different nonstandard amino acids (claim 40)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 39 is generic.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
June 17, 2002

OC



JOHN ULM
PRIMARY EXAMINER
GROUP 1800